

REMARKS

This Amendment accompanies a Request for Continued Examination (RCE).

Reconsideration of this application is requested. Claims 18-22 and 24-34 are active in the application subsequent to entry of this Amendment.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention by specifying that the benzimidazole compound (A) is rabeprazole, the component (B) is sodium hydroxide and that the proportion of (A) to (B) is from 0.01 to 2 parts by weight based on the description in the specification at page 7, lines 22-24. In consequence of these changes, claims 16 and 17 have been withdrawn as being redundant while the dependencies of claims 18-20 and 24-26 have been adjusted to reflect the removal of claims 16 and 17. In addition, previous independent claims 32 and 33 have been revised to depend from either claim 21 or 22. New claim 34 is directed to a preferred aspect of the invention in which the lower amount of (B) is 0.01 (see Examples 19 and 20) and the upper limit is 0.05 (see Examples 24-27).

Submitted with this response is the Evidentiary Declaration of Mr. Yoshiteru Kato made October 30, 2002.

This evidence includes tests in which sodium citrate and sodium phosphate as sodium anion, aluminium hydroxide, calcium hydroxide and magnesium hydroxide as hydroxide cation were used for stabilizing rabeprazole. The stabilizing tests were conducted at 60°C, 40°C, 75%RH/stored for one week. Results were evaluated in terms of rabeprazole's content, degradation products and color difference.

From the test results it will be apparent that rabeprazole was unexpectedly more effectively stabilized in Examples 2 and 3, in which 0.5 or 1.0 part of NaOH was used per 10 of rabeprazole, than in Examples 5, 7, 9, 11 and 13 using other alkali compounds in an amount of 0.5 part.

The claimed invention provides an unexpected improvement in stabilization by adding a relatively small amount of NaOH. Other alkali compounds afforded no improvement when used in so small an amount.

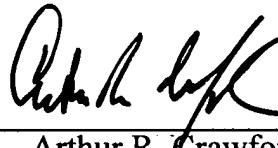
Favorable consideration of this evidence and the claim amendments made above are solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page(s) is captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

18. (Amended) A pharmaceutical preparation comprising a core consisting of the composition as claimed in claim [16] 21 or 22 and an enteric coating thereon.

19. (Amended) A pharmaceutical preparation comprising a core consisting of the composition as claimed in claim [16] 21 or 22, an intermediate coating and an enteric coating.

20. (Amended) A pharmaceutical preparation comprising a core consisting of the composition as claimed in claim [16] 21 or 22, an intermediate coating, an enteric coating and a moisture resistant coating.

21. (Amended) A composition comprising (A) rabeprazole or an alkali metal salt thereof and (B) [is at least one member selected from the group consisting of] sodium hydroxide, [and potassium hydroxide] wherein the composition comprises 1 part by weight of (A) and 0.01 to 2 parts by weight of (B).

22. (Amended) A composition comprising (A) [rabeprozole] rabeprazole or an alkali metal salt thereof, (B) crospovidone and [at least one member selected from the group consisting of] sodium hydroxide [and potassium hydroxide], wherein the composition comprises 1 part by weight of (A), 0.01 to 2 parts by weight of sodium hydroxide and 0.5 to 5 parts by weight of crospovidone.

24. (Amended) The pharmaceutical composition of claim [16,] 21 or 22 wherein components (A) and (B) are uniformly mixed with each other.

25. (Amended) The pharmaceutical composition of claim [16,] 21 or 22 wherein (A) is mixed with a portion of (B) to form granules, then a further amount of (B) is added to the granules and mixed, then the mixture is formed into a tablet.

26. (Amended) The pharmaceutical composition of claim [16,] 21 or 22 wherein (A) is mixed with a portion of (B) and formed into a core, then a further amount of (B) is coated as a layer onto the core.

31. (Amended) The pharmaceutical preparation according to any one of claims 27, 28 [and] or 29, wherein the core further comprises an antioxidant.

32. (Amended) A pharmaceutical preparation comprising a core which comprises the composition of claim 21 or 22 [a drug incorporated into it, the drug being accelerated in decomposition in the presence of water and chemically unstable in gastric acid,] coated with an enteric coating and further with a moisture-resistant coating.

33. (Amended) A pharmaceutical preparation comprising a core which comprises the composition of claim 21 or 22 [a drug incorporated into it, the drug being accelerated in decomposition in the presence of water and chemically unstable in gastric acid,] coated with an intermediate coating, further with an enteric coating and then with a moisture-resistant coating.